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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E INC., Plaintiffs, v. RANBAXY PHARMACEUTICALS, INC. RANBAXY INC. and RANBAXY LABORATORIES LTD. Defendants.	Civil Action No. _____

COMPLAINT

JURISDICTION AND VENUE

1. This is an action for patent infringement and a declaratory judgment arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code. Jurisdiction and venue are based on 28 U.S.C. §§ 1331, 1338(a), 1391(b), 1391(c), 1400(b), 2201, 2202 and 35 U.S.C. § 271.

2. On information and belief, Ranbaxy Laboratories Ltd., Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Inc. (jointly and severally "Ranbaxy") have been and are engaging in activities directed toward infringement of United States Patent Nos. 5,714,504 (the "'504 patent"); 5,877,192 (the "'192 patent"); 6,875,872 (the "'872 patent"); 6,428,810 (the "'810 patent"); 6,369,085 (the "'085 patent"); 5,948,789 (the "'789 patent"), by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 77-830 and by submitting Drug Master Files (DMF) seeking FDA's approval to manufacture commercially its proposed 20 mg and 40 mg product called "Esomeprazole Magnesium" (herein after referred to as "Esomeprazole Magnesium Capsules") containing the active ingredient esomeprazole magnesium.

3. In Ranbaxy's notice letter entitled "Esomeprazole Magnesium Delayed-Release Capsules, 20 mg and 40 mg, ANDA No. 77-830, U.S. Patent Nos. 4,738,974; 4,786,505; 4,853,230; 5,690,960; 5,714,504; 5,877,192; 5,900,424; 6,147,103; 6,166,213; 6,191,148; 6,369,085; 6,428,810 and 6,875,872" (hereinafter referred to as the "Notice of Certification"), Ranbaxy has indicated that it intends to market its Esomeprazole Magnesium Capsules before the expiration of the '504, '192, '872, '810, '085 and '789 patents.

4. Ranbaxy's submission of ANDA No. 77-830 and the DMF, in addition to service of its Notice of Certification, indicates a refusal to change its current course of action.

5. There has been and is now an actual controversy between Ranbaxy and Plaintiffs as to whether Ranbaxy infringes the '504, '192, '872, '810, '085 and '789 patents.

THE PARTIES

6. Plaintiff AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden. AstraZeneca AB was a corporate name change from Astra Aktiebolaget.

7. Plaintiff Aktiebolaget Hässle ("Hässle") is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

8. Plaintiff AstraZeneca LP is a limited partnership organized under the laws of Delaware having its principal place of business at Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the United States Food and Drug Administration ("FDA") for an esomeprazole magnesium formulation which it sells under the name NEXIUM®.

9. Plaintiff KBI Inc. ("KBI") is a Delaware corporation having it principal place of business at Whitehouse Station, New Jersey.

10. Plaintiff KBI-E Inc. ("KBI-E") is a Delaware corporation, having its principal place of business at Wilmington, Delaware. KBI and KBI-E have exclusive rights in the United States to patents-in-suit.

11. On information and belief, defendant Ranbaxy Laboratories Ltd. is a public limited liability company organized and existing under the laws of India, having corporate headquarters in Haryana, India.

12. On information and belief, defendant Ranbaxy Pharmaceuticals, Inc. is a Florida corporation, having a principal place of business at 9431 Florida Mining Blvd. East, Jacksonville, Florida and having a place of business at 600 College Road East, Suite 2100, Princeton, New Jersey.

13. On information and belief, defendant Ranbaxy Inc. is a Delaware corporation, having a place of business at 600 College Road East, Suite 2100, Princeton, New Jersey.

14. On information and belief, Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Inc. are wholly owned subsidiaries of Ranbaxy Laboratories Ltd. and act as the agents of Ranbaxy Laboratories Ltd. in the United States.

15. On information and belief, Ranbaxy Laboratories Ltd., Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Inc. (jointly and severally "Ranbaxy") are doing business in New Jersey, have continuous and systematic contacts with New Jersey, have engaged in activities together related to the subject matter of this action and are subject to personal jurisdiction in this judicial district.

FIRST CLAIM FOR RELIEF: '504 PATENT

16. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, "Plaintiffs") reallege paragraphs 1-15, above, as if set forth specifically here.

17. The '504 patent (copy attached as Exhibit "A"), entitled "Compositions," was issued on February 3, 1998 to Astra Aktiebolag upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The patent was subsequently assigned to AstraZeneca AB. The '504 patent claims, *inter alia*, pharmaceutical formulations comprising

alkaline salts of esomeprazole (including esomeprazole magnesium) and methods of using esomeprazole magnesium.

18. Plaintiff AstraZeneca AB has been and is still the owner of the '504 patent. The '504 patent will expire on February 3, 2015 and pediatric exclusivity relating to the '504 patent expires on August 3, 2015.

19. Ranbaxy's Notice of Certification notified Plaintiffs that it had submitted an Abbreviated New Drug Application ("ANDA") to the FDA under 21 U.S.C. § 355(j), seeking the FDA's approval to manufacture, use, offer to sell and sell Ranbaxy's Esomeprazole Magnesium Capsules as a generic version of the NEXIUM® product.

20. In the Notice of Certification, Ranbaxy notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '504 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '504 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

21. On information and belief, at the time Ranbaxy's Notice of Certification was served, Ranbaxy was aware of the statutory provisions and regulations referred to in paragraph 20, above.

22. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 20 above), does not allege non-infringement of all claims of the '504 patent.

23. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 20 above), does not allege invalidity of all claims of the '504 patent.

24. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 20 above), does not address unenforceability or inequitable conduct of the '504 patent.

25. In the Notice of Certification, Ranbaxy did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 20, above, as to the '504 patent.

26. Ranbaxy's Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

27. Ranbaxy has infringed the '504 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, or the use of which is claimed in the this patent, prior to the expiration of the '504 patent.

28. On information and belief, Ranbaxy's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients in a therapeutically effective

amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Ranbaxy's active behest and with its intent, knowledge and encouragement. On information and belief, Ranbaxy will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '504 patent.

29. On information and belief, Ranbaxy's Esomeprazole Magnesium Capsules are especially made or especially adapted to inhibit gastric acid secretion and for use in the treatment of gastrointestinal inflammatory disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the claimed esomeprazole magnesium and a pharmaceutically acceptable carrier. On information and belief, Ranbaxy is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Ranbaxy is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '504 patent.

30. Ranbaxy's Notice of Certification does not allege and does not address non-infringement of claims 1-3 and 5-10 of the '504 patent. By not addressing non-infringement of claims 1-3 and 5-10 of the '504 patent in its Notice of Certification, Ranbaxy admits that its Esomeprazole Magnesium Capsules meet all limitations of claims 1-3 and 5-10 of the '504 patent.

31. On information and belief, the manufacture, use and sale of Ranbaxy's Esomeprazole Magnesium Capsules infringe the '504 patent claims.

32. To further investigate whether Ranbaxy's Esomeprazole Magnesium Capsules infringe the '504 patent claims, in a letter dated October 25, 2005, AstraZeneca requested access to certain documents, information and samples, as well as access to Ranbaxy's ANDA No. 77-830 and the DMF.

33. AstraZeneca requested the information and samples to "evaluate the representations made in Ranbaxy's Notice Letter and the products and patents referred to therein and not for other purposes."

34. AstraZeneca informed Ranbaxy that ANDA No. 77-830 and the DMF were not sufficient to evaluate the allegations in the Notice of Certification. Despite this, Ranbaxy refused to agree to provide AstraZeneca access to any documents other than Ranbaxy's ANDA No. 77-830 and the DMF, including refusing to provide access to any of the requested samples.

35. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain under appropriate judicial safeguards information to confirm that Ranbaxy's Esomeprazole Magnesium Capsules infringe the '504 patent claims.

SECOND CLAIM FOR RELIEF: '192 PATENT

36. Plaintiffs reallege paragraphs 1-15 and 19, above, as if set forth specifically here.

37. The '192 patent, (copy attached as Exhibit "B"), entitled "Method For The Treatment Of Gastric Acid-Related Diseases And Production Of Medication Using (-)Enantiomer Of Omeprazole," was issued on March 2, 1999 to Astra Aktiebolag, upon assignment from the inventors Per Lindberg and Lars Weidolf. The patent was subsequently assigned to AstraZeneca AB. The '192 patent claims, *inter alia*, methods for treatment of gastric acid related diseases by administering a therapeutically effective amount of esomeprazole and pharmaceutically acceptable salts thereof and methods for producing a medicament for such treatment.

38. Plaintiff AstraZeneca AB has been and still is the owner of the '192 patent. The '192 patent will expire on May 27, 2014 and pediatric exclusivity relating to the '192 patent expires on November 27, 2014.

39. In the Notice of Certification, Ranbaxy notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '192 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '192 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

40. On information and belief, at the time Ranbaxy's Notice of Certification was served, Ranbaxy was aware of the statutory provisions and regulations referred to in paragraph 39, above.

41. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 39 above), does not allege non-infringement of all claims of the '192 patent.

42. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 39 above), does not address unenforceability or inequitable conduct of the '192 patent.

43. In the Notice of Certification, Ranbaxy did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 39, above, as to the '192 patent.

44. Ranbaxy's Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

45. Ranbaxy has infringed the '192 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug the use of which is claimed in this patent, prior to the expiration of the '192 patent.

46. On information and belief, Ranbaxy's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related diseases by inhibiting gastric acid secretion. On information and belief such administration will effect decreased interindividual variation in plasma levels (AUC) during such treatment. On information and belief such treatment will effect increased average plasma levels(AUC) per dosage unit. On information and belief such treatment will effect a pronounced increase in gastrin levels in slow metabolisers during such treatment. On information and belief such treatment will effect decreased CYP1A induction in slow metabolisers during such treatment. On information and belief such treatment will elicit an improved antisecretory effect during such treatment. On information and belief such treatment will elicit an improved clinical effect comprising accelerated rate of healing and accelerated rate

of symptom relief during such treatment. On information and belief the amount to be administered will be between about 20 mg and about 40 mg total daily dose during such treatment. On information and belief, this administration will occur at Ranbaxy's active behest and with its intent, knowledge and encouragement. On information and belief, Ranbaxy will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '192 patent.

47. On information and belief, Ranbaxy's Esomeprazole Magnesium Capsules are especially made or especially adapted to inhibit gastric acid secretion and for use in the treatment of gastrointestinal inflammatory disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the magnesium salt of esomeprazole. On information and belief, Ranbaxy is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Ranbaxy is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '192 patent.

48. Ranbaxy's Notice of Certification does not allege and does not address non-infringement of claims 1-7, 10-19, 21-22 (as dependent from claims 12-19) and 23 of the '192 patent. By not addressing non-infringement of claims 1-7, 10-19, 21-22 (as dependant from claims 12-19) and 23 of the '192 patent in its Notice of Certification, Ranbaxy admits that its manufacture and sale of Esomeprazole Magnesium Capsules meets all limitations in those claims.

49. On information and belief, the manufacture, use and sale of Ranbaxy's Esomeprazole Magnesium Capsules infringe the '192 patent claims.

50. To further investigate whether Ranbaxy's Esomeprazole Magnesium Capsules infringe the '192 patent claims, in a letter dated October 25, 2005,

AstraZeneca requested access to certain documents, information and samples, as well as access to Ranbaxy's ANDA No. 77-830 and the DMF.

51. AstraZeneca requested the information and samples to "evaluate the representations made in Ranbaxy's Notice Letter and the products and patents referred to therein and not for other purposes."

52. AstraZeneca informed Ranbaxy that ANDA No. 77-830 and the DMF were not sufficient to evaluate the allegations in the Notice of Certification. Despite this, Ranbaxy refused to agree to provide AstraZeneca access to any documents other than Ranbaxy's ANDA No. 77-830 and the DMF, including refusing to provide access to any of the requested samples.

53. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain under appropriate judicial safeguards information to confirm that Ranbaxy's Esomeprazole Magnesium Capsules infringe the '192 patent claims.

THIRD CLAIM FOR RELIEF: '872 PATENT

54. Plaintiffs reallege paragraphs 1-15 and 19, above, as if set forth specifically here.

55. The '872 patent, (copy attached as Exhibit "C"), entitled "Compounds," was issued on April 5, 2005 to AstraZeneca AB, upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The '872 patent claims, *inter alia*, esomeprazole magnesium salts.

56. Plaintiff AstraZeneca AB has been and still is the owner of the '872 patent. The '872 patent will expire on May 27, 2014 and pediatric exclusivity relating to the '872 patent expires on November 27, 2014.

57. In the Notice of Certification, Ranbaxy notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '872 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '872 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

58. On information and belief, at the time Ranbaxy's Notice of Certification was served, Ranbaxy was aware of the statutory provisions and regulations referred to in paragraph 57, above.

59. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 57 above), does not allege non-infringement of all the claims of the '872 patent.

60. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 57 above), does not allege invalidity of all the claims of the '872 patent.

61. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 57 above), does not address unenforceability or inequitable conduct of the '872 patent.

62. In the Notice of Certification, Ranbaxy did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 57, above, as to the '872 patent.

63. Ranbaxy's Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

64. Ranbaxy has infringed the '872 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, prior to the expiration of the '872 patent.

65. On information and belief, Ranbaxy's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients at Ranbaxy's active behest and with its intent, knowledge and encouragement. On information and belief, Ranbaxy will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '872 patent.

66. On information and belief, Ranbaxy's Esomeprazole Magnesium Capsules are especially made or especially adapted for treatment of humans. On information and belief, Ranbaxy is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Ranbaxy is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '872 patent.

67. Ranbaxy's Notice of Certification does not allege and does not address non-infringement of claims 1, 2, 4, 5, 7, 8, 10 and 11 of the '872 patent. By not

addressing non-infringement of claims 1, 2, 4, 5, 7, 8, 10 and 11 of the '872 patent in its Notice of Certification, Ranbaxy admits that its Esomeprazole Magnesium Capsules meets all limitations in claims 1, 2, 4, 5, 7, 8, 10 and 11 of the '872 patent.

68. On information and belief, the manufacture, use and sale of Ranbaxy's Esomeprazole Magnesium Capsules infringe the '872 patent claims.

69. To further investigate whether Ranbaxy's Esomeprazole Magnesium Capsules infringe the '872 patent claims, in a letter dated October 25, 2005, AstraZeneca requested access to certain documents, information and samples, as well as access to Ranbaxy's ANDA No. 77-830 and the DMF.

70. AstraZeneca requested the information and samples to "evaluate the representations made in Ranbaxy's Notice Letter and the products and patents referred to therein and not for other purposes."

71. AstraZeneca informed Ranbaxy that ANDA No. 77-830 and the DMF were not sufficient to evaluate the allegations in the Notice of Certification. Despite this, Ranbaxy refused to agree to provide AstraZeneca access to any documents other than Ranbaxy's ANDA No. 77-830 and the DMF, including refusing to provide access to any of the requested samples.

72. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain under appropriate judicial safeguards information to confirm that Ranbaxy's Esomeprazole Magnesium Capsules infringe the '872 patent claims.

FOURTH CLAIM FOR RELIEF: '810 PATENT

73. Plaintiffs reallege paragraphs 1-15 and 19, above, as if set forth specifically here.

74. The '810 patent, (copy attached as Exhibit "D"), entitled "Pharmaceutical Formulation Comprising Omeprazole," was issued on August 6, 2002 to AstraZeneca AB, upon assignment from the inventors Pontus Bergstrand and Peter Wang. The '810 patent claims, *inter alia*, pharmaceutical formulations for esomeprazole magnesium and methods for treatment using the formulation.

75. Plaintiff AstraZeneca AB has been and still is the owner of the '810 patent. The '810 patent will expire on November 3, 2019 and pediatric exclusivity relating to the '810 patent expires on May 3, 2020.

76. In the Notice of Certification, Ranbaxy notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '810 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '810 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

77. On information and belief, at the time Ranbaxy's Notice of Certification was served, Ranbaxy was aware of the statutory provisions and regulations referred to in paragraph 76, above.

78. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 76 above), does not allege invalidity of any claims of the '810 patent.

79. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 76 above), does not address unenforceability or inequitable conduct of the '810 patent.

80. In the Notice of Certification, Ranbaxy did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 76, above, as to the '810 patent.

81. Ranbaxy's Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

82. Ranbaxy has infringed the '810 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, or the use of which is claimed in this patent, prior to the expiration of the '810 patent.

83. On information and belief, the Ranbaxy Esomeprazole Magnesium Capsules, if approved, will be administered to human patients in a therapeutically effective amount to treat gastrointestinal diseases. On information and belief, this administration will occur at Ranbaxy's active behest and with its intent, knowledge and encouragement. On

information and belief, Ranbaxy will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '810 patent.

84. On information and belief, the Ranbaxy Esomeprazole Magnesium Capsules are especially made or especially adapted to treat gastrointestinal diseases through administration to humans in need of such treatment via the administration of a therapeutically effective amount of the Ranbaxy Esomeprazole Magnesium Capsules pharmaceutical formulation. On information and belief, Ranbaxy is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Ranbaxy is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '810 patent.

85. On information and belief, the manufacture, use and sale of Ranbaxy's Esomeprazole Magnesium Capsules infringe the '810 patent claims.

86. To further investigate whether Ranbaxy's Esomeprazole Magnesium Capsules infringe the '810 patent claims, in a letter dated October 25, 2005, AstraZeneca requested access to certain documents, information and samples, as well as access to Ranbaxy's ANDA No. 77-830 and the DMF.

87. AstraZeneca requested the information and samples to "evaluate the representations made in Ranbaxy's Notice Letter and the products and patents referred to therein and not for other purposes."

88. AstraZeneca informed Ranbaxy that ANDA No. 77-830 and the DMF were not sufficient to evaluate the allegations in the Notice of Certification. Despite this, Ranbaxy refused to agree to provide AstraZeneca access to any documents other than Ranbaxy's ANDA No. 77-830 and the DMF, including refusing to provide access to any of the requested samples.

89. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain under appropriate judicial safeguards information to confirm that Ranbaxy's Esomeprazole Magnesium Capsules infringe the '810 patent claims.

FIFTH CLAIM FOR RELIEF: '085 PATENT

90. Plaintiffs reallege paragraphs 1-15 and 19, above, as if set forth specifically here.

91. The '085 patent, (copy attached as Exhibit "E"), entitled "Form of S-Omeprazole," was issued on April 9, 2002 to AstraZeneca AB, upon assignment from the inventors Hanna Cotton, Anders Kronström, Anders Mattson and Eva Möller. The '085 patent claims, *inter alia*, magnesium salts of esomeprazole trihydrate, pharmaceutical compositions comprising the claimed salts, methods of treatment using the claimed salts, and processes for preparing the claimed salts.

92. Plaintiff AstraZeneca AB has been and still is the owner of the '085 patent. The '085 patent will expire on May 25, 2018 and pediatric exclusivity relating to the '085 patent expires on November 25, 2018.

93. In the Notice of Certification, Ranbaxy notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '085 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '085 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules

and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

94. On information and belief, at the time Ranbaxy's Notice of Certification was served, Ranbaxy was aware of the statutory provisions and regulations referred to in paragraph 93, above.

95. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 93 above), does not allege invalidity of any claims of the '085 patent.

96. Ranbaxy's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 93 above), does not address unenforceability or inequitable conduct of the '085 patent.

97. In the Notice of Certification, Ranbaxy did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 93, above, as to the '085 patent.

98. Ranbaxy's Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

99. Ranbaxy has infringed the '085 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture,

use or sale of a drug claimed in this patent, or the use of which is claimed in this patent, prior to the expiration of the '085 patent.

100. On information and belief, Ranbaxy's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related conditions. On information and belief, this administration will occur at Ranbaxy's active behest and with its intent, knowledge and encouragement. On information and belief, Ranbaxy will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '085 patent.

101. On information and belief, Ranbaxy's Esomeprazole Magnesium Capsules are especially made or especially adapted to treat gastric acid related diseases via the administration of a therapeutically effective amount of a pharmaceutical formulation containing esomeprazole. On information and belief, Ranbaxy is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Ranbaxy is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '085 patent.

102. On information and belief, the manufacture, use and sale of Ranbaxy's Esomeprazole Magnesium Capsules infringe the '085 patent claims.

103. To further investigate whether Ranbaxy's Esomeprazole Magnesium Capsules infringe the '085 patent claims, in a letter dated October 25, 2005, AstraZeneca requested access to certain documents, information and samples, as well as access to Ranbaxy's ANDA No. 77-830 and the DMF.

104. AstraZeneca requested the information and samples to "evaluate the representations made in Ranbaxy's Notice Letter and the products and patents referred to therein and not for other purposes."

105. AstraZeneca informed Ranbaxy that ANDA No. 77-830 and the DMF were not sufficient to evaluate the allegations in the Notice of Certification. Despite this, Ranbaxy refused to agree to provide AstraZeneca access to any documents other than Ranbaxy's ANDA No. 77-830 and the DMF, including refusing to provide access to any of the requested samples.

106. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain under appropriate judicial safeguards information to confirm that Ranbaxy's Esomeprazole Magnesium Capsules infringe the '085 patent claims.

SIXTH CLAIM FOR RELIEF: '789 PATENT

107. Plaintiffs reallege paragraphs 1-15 and 19, above, as if set forth specifically here.

108. United States Patent No. 5,948,789 (the "'789 patent," copy attached as Exhibit "F"), entitled "Process For Synthesis Of Substituted Sulphoxides," was issued on September 7, 1999 to Astra Aktiebolag, upon assignment from the inventors Magnus Erik Larsson, Urban Jan Stenhede, Henrik Sörensen, Sverker Per Oskar von Unge and Hanna Kristina Cotton. The patent was subsequently assigned to AstraZeneca AB. The '789 patent claims, *inter alia*, processes for the synthesis of sulfoxide compounds.

109. Plaintiff AstraZeneca AB has been and still is the owner of the '789 patent. The '789 patent will expire on July 3, 2015.

110. Ranbaxy submitted to FDA on an Abbreviated New Drug Application, No. 77-830, seeking FDA's approval to manufacture, use and sell Ranbaxy's proposed Esomeprazole Magnesium Capsules as a generic version of the NEXIUM® Delayed-Release Capsules.

111. On information and belief, the process Ranbaxy uses to manufacture the active ingredient in its Esomeprazole Magnesium Capsules will infringe the claims of the '789 patent.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Ranbaxy's ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug product "Esomeprazole magnesium" must be later than May 3, 2020, the expiration date of the last patent in suit, including pediatric exclusivity relating to the patent, that is infringed;

(b) A judgment declaring that the '504, '192, '872, '810, '085 and '789 patents remain valid, remain enforceable and have been infringed by defendant Ranbaxy;

(c) A judgment declaring that Ranbaxy have not complied with the requirements of 35 U.S.C. § 271(e)(2), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), 21 U.S.C. § 355(j)(2)(B)(iv), 21 C.F.R. § 314.94 and 21 U.S.C. § 314.95;

(d) A permanent injunction against any infringement by Ranbaxy of the '504, '192, '872, '810, '085 and '789 patents;

(e) A judgment that Ranbaxy's infringement is willful;

(f) A judgment that Ranbaxy's conduct is exceptional;

(g) Attorneys' fees in this action under 35 U.S.C. § 285;

(h) Costs and expenses in this action; and

(i) Such other relief as this Court may deem proper.

Dated: November 21, 2005

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